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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,166	04/26/2001	Edward W. Merrill	37697-0035	7738

7590

08/11/2003

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/842,166

Applicant(s)

MERRILL ET AL.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 124-149 is/are pending in the application.
- 4a) Of the above claim(s) 137-149 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 124-136 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Prosecution Application

The request filed on May 30, 2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/842,166 is acceptable and a CPA has been established. An action on the CPA follows.

Response to Arguments

Applicant's arguments with respect to claims 124-136 have been considered but are moot in view of the new ground(s) of rejection.

Applicant has argued that McKellop et al. (USPN 6,165,220) is not prior art. Applicant has provided proof that the subject matter contained in the examined claims is disclosed in applicant's parent application 08/726,313. Applicant's argument is persuasive and the examiner agrees with the applicant.

Applicant has argued that the Saum et al. (USPN 6,017,975) is not prior art. Applicant has provided proof that the subject matter contained in the examined claims is disclosed in applicant's parent application 08/726,313. Applicant's argument is persuasive and the examiner agrees with the applicant.

Applicant has argued that Lemstra (USPN 5,066,755) does not disclose the generation of multiple melting peaks by irradiation. The examiner disagrees. The examiner points the applicant to figure 3 and to col.20, line 66-col.21, line 12. Lemstra compares non-irradiated UHMWPE to irradiated UHMWPE. Lemstra discloses that non-irradiated UHMWPE produces one melting peak and the irradiated UHMWPE produces two melting peak, wherein the irradiation causes changes to the melting behavior of the polymer.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 124-129 and 131-136 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemstra (USPN 5,066,755, cited in previous office action). Referring to claims 124 and 132, Lemstra discloses irradiation treated UHMWPE (col.19, lines 39-42) having cross-links (col.4, lines 16-21) and multiple melting peaks (curve D in fig.3; col.20, line66-col.21, line 12). Lemstra discloses the UHMWPE used for medical prostheses (col.12, line 38).

Referring to claims 126 and 134, Lemstra discloses UHMWPE having two melting peaks (fig.3, curve D; col.20, line 61-col.21, line 16).

Referring to claims 125 and 133, Lemstra discloses irradiation causing change in the melting behavior of the UHMWPE (col.20, lines 21-24; col.21, lines 14-16), by production of multiple melting peaks (col.20, line 63-col.21, line 16; fig.3, curve D). Lemstra does not show three melting peaks, however since Lemstra discloses irradiation of the same material and the same radiation dosage, and variation of dosages to produce desired properties (col.14, lines 12-16) inherently the same product with three melting peaks will be produced.

Referring to claims 127 and 135, Lemstra discloses irradiation at the same dosages disclosed by the applicant (col.7, lines 61-63, therefore, inherently heating will occur.

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Referring to claim 128, Lemstra discloses the UHMWPE having increased cross linkage (col.22, lines 38-43) such that a substantial portion of the polymeric structure does not dissolve in xylene at 130C or DECALIN at 150C over a period of 24 hours (col.9, line 64-col.10, line 20; col.4, line 51).

Referring to claim 129, Lemstra discloses UHMWPE having an initial average molecular weight of greater than about 1 million (col.8, lines 45-46, 54-58; col.9, line 1).

Referring to claims 131 and 136, Lemstra discloses irradiation of UHMWPE at the same dosage (col.7, lines 61-63) as disclosed by the applicant and discloses irradiation affect properties such as crystallinity and tensile modulus (col.4, lines 1-8), therefore, the end product will inherently possess the same properties.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 130 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lemstra (USPN 5,066,755, cited in previous office action) in view of Salovey et al. (USPN 6,281,264, cited in previous office action). Lemstra discloses irradiated UHMWPE (col.19, lines 39-42) with multiple melting peaks (curve D in fig.3; col.20, line 66-col.21, line 16) and cross-links (col.4, lines 16-21) used as medical products (col.12, line 38), however does not explicitly disclose what type of medical applications, such as joint replacements. Salovey teaches in the field of joint replacement materials, use of irradiated UHMWPE materials for joint replacements in order to

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provide a material with increased wear resistance, which provides longevity of the prosthesis (col.1, lines 18-24; col.6, lines 1-4, 22-27). It would have been obvious to combine Lemstra's irradiated UHMWPE having cross-links and multiple melting peaks with Salovey's teaching of using irradiated UHMWPE materials for joint replacements in order to produce a prosthesis having increased wear resistance and creating longevity of the prosthesis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Cheryl Miller

August 6, 2003



BRUCE SNOW
PRIMARY EXAMINER